

## Amended Biodiversity Act: implications for intellectual property protection and technology transfer

Akriti Sharma

*In accordance with international conventions and protocols, countries are modifying their biodiversity regulations. India's 2023 amendment to the Biological Diversity Act focuses on access and benefit sharing (fairly dividing benefits from using biological resources) concerning biodiversity. The amendment introduces new rules to simplify managing intellectual property rights and technology transfer while encouraging researchers to participate in these areas. This article compares the original and amended acts, explaining how the changes affect research institutions working with biological resources.*

Biodiversity, comprising plants, animals and microbes, is crucial for the health of ecosystem and its stability. However, anthropogenic activities like deforestation, habitat degradation and pollution, have led to a rapid decline in global biodiversity. To address this issue and protect our natural heritage for future generations, the Biological Diversity Act (BDA) was introduced in 2002 in India. Section 2(b) of the BDA 2002 defines 'biological diversity' as 'the variability among living organisms from all sources and the ecological complexes of which they are part and includes diversity within species or between species and of eco-systems.'

Agricultural research institutions play a crucial role in biodiversity conservation by conducting research and developing sustainable farming practices that promote the preservation of diverse ecosystems. They work towards identifying and conserving plant and animal species, as well as their habitats, while promoting the use of indigenous and traditional knowledge in agricultural practices to maintain biodiversity. These institutions, in their research, use various biological resources, such as seed varieties, biocontrol agents, etc. Often, they transfer their research results (technologies) to private companies for large-scale production and sale to farmers and others. This ensures rapid and wider dissemination of technologies among the user masses.

The original BDA (2002) had certain rules for protecting intellectual property rights (IPR) and transferring biological resources to private companies. However, these rules presented some practical challenges. In July 2023, significant amendments were made to the Act, and the new Act is designated as Biological Diversity (Amendment) Act, 2023. Here we explore how the amended BDA helps protect intellectual property and licensing of biological resources to private parties.

### Origin of BDA

India's BDA resulted from its commitment to the Convention on Biological Diversity (CBD) signed in 1992. The CBD's primary goal is to promote the conservation and responsible use of biological resources. To fulfil its obligations under the CBD, India established the BDA as a mechanism with a three-tiered implementation system:

- The National Biodiversity Authority (NBA) at the central level.
- State Biodiversity Boards (SBBs) at the state level.
- Biodiversity Management Committees (BMCs) at the local level.

### Significant changes in the amended act

The BDA regulates access and benefit sharing (ABS) in India, which outlines how biological resources can be used for various purposes, including scientific research and commercial activities, along with fair and equitable sharing of benefits arising from their utilization. However, the specific details and mechanisms for implementing ABS were established later in the Nagoya Protocol, signed in 2010 by 92 countries, including India and the obligations of India as a party to the Nagoya Protocol were not covered by the original BDA because it was drafted in 2002, long time before the Nagoya Protocol. The amended act rectifies this by clarifying how Indians and foreigners (including companies) can access biological resources and how benefits from their commercial use can be shared among the stakeholders.

### Regulation of access to biological diversity

The most significant changes in the amendment concern intellectual property protection

and commercializing research outputs derived from biological resources by Indian and foreign entities.

Previously, according to section 3(2), c(ii) of the old act required that any company registered in India with any foreign involvement in its ownership or management required approval from the NBA to access biological resources or related knowledge within India for research or commercial use. This meant even Indian companies with some foreign investment had to obtain NBA clearance before accessing biological resources. Research institutions also needed NBA approval to transfer biological resources to such companies. This process was time-consuming and hindered access to biological resources, even for Indian companies. Additionally, private entities were losing market share due to the cumbersome procedure, while research institutions struggled to effectively distribute resources and knowledge.

The amended act simplifies this process. Now, only entities 'controlled' by foreigners, as defined under the Companies Act 2013, need NBA approval for access to biological resources in India. Indian companies with foreign shareholders but with Indian control, can access resources and transfer research results without NBA approval.

### Regulation to obtain intellectual property rights

The old act required everyone to get approval from the NBA before filing patents based on biological resources (except for plant varieties). This meant researchers working with microbes or other biological resources had to undergo an extra step before filing a patent application.

The amended Act (section 6(1)) simplifies this process. Now, only foreign entities (including individuals and companies)

need NBA approval before they can be granted IPR based on biological resources found in India.

Indian nationals and entities, on the other hand, only need to register with the NBA before obtaining IPR. However, they must inform the relevant SBB before commercially using the IPR (sections 23(b) and 24(2)). This streamlined process should expedite patent applications for Indian researchers and institutions.

### Other considerations

The amended act does not provide access to 'codified traditional knowledge', which refers to the knowledge documented in authoritative books listed under the Drugs and Cosmetics Act of 1940 related to Indian traditional medicine systems like ayurveda, siddha, unani, etc.

Further, the amended act exempts registered AYUSH practitioners (practitioners of Indian traditional medicine systems), local communities, and cultivators of medicinal plants and their derivatives from giving prior SBB intimation for commercially utilizing such knowledge (sections 7 and 40). These exemptions aim to support the livelihood of these communities and practitioners.

### Procedure simplification

The amended act simplifies the procedure for obtaining approval for ABS by using

Forms I through IV. These forms are submitted to the NBA by different entities seeking permission for various activities.

- Form I: Used by the foreign 'controlled' entities/individuals to request authorization for accessing biological resources and associated traditional knowledge.
- Form II: Used by research institutions to seek prior authorization to disclose research findings to foreign individuals or entities, companies operating abroad and NRIs for commercial purposes.
- Form III: Used by researchers to request pre-authorization to pursue patent applications.
- Form IV: Used to appeal against the endorsement granted by the NBA for the transfer of accessed biological resources and associated traditional knowledge to a third party.

### Implications and conclusion

The implications of these amendments are significant for individuals or entities seeking to engage in activities related to biological resources and traditional knowledge. By requiring pre-authorization and endorsement from the NBA in specific contexts, the amendments ensure that proper regulations and guidelines are

followed, promoting responsible and sustainable utilization of bio-resources. For Indian entities, the amendments streamline the process of obtaining IPR and patents. Additionally, the act clarifies the roles and functions of the NBA and SBB. Overall, the amendments aim to simplify technology transfer between research institutions and Indian companies, while still protecting the rights of local communities and indigenous knowledge holders.

1. The Biological Diversity Act, 2002; <https://ddashboard.legislative.gov.in/actsofparliamentfromtheyear/biological-diversity-act-2002> (accessed on 12 September 2023).
2. The Biological Diversity (Amendment) Act, 2023; <https://egazette.gov.in/WriteReadData/2023/247815.pdf> (accessed on 12 September 2023).
3. The Companies Act, 2013; <https://www.mca.gov.in/Ministry/pdf/CompaniesAct2013.pdf> (accessed on 12 September 2023).
4. The Drugs and Cosmetics Act, 1940; [https://www.indiacode.nic.in/bitstream/123456789/15278/1/drug\\_cosmetics1940-23.pdf](https://www.indiacode.nic.in/bitstream/123456789/15278/1/drug_cosmetics1940-23.pdf) (accessed on 12 September 2023).

*Akriti Sharma is in the ICAR-Indian Agricultural Research Institute, New Delhi 110 012, India.  
e-mail: aakritinankur@gmail.com*

## Mental health of India's ageing population: what do we know?

*Suman Ray and Rupali Sharma*

United Nations General Assembly in 2020 declared the period from 2021 to 2030 as the Decade of Healthy Ageing. The announcement came in the wake of changing population demography globally. Population ageing, the increase in the proportion of population in the older age group is the most significant global trend. It presents key challenges and concerns not only to the people of older age group but to the whole society. Increased longevity, along with decreasing fertility rates are the main reasons for the changes in population growth and age distribution<sup>1</sup>.

Globally, there were 771 million people aged 65 years and above in 2022 (ref. 2).

As per the latest projections, the number of persons aged 65 years and above will rise to 994 million by 2030. According to the WHO estimates, by the year 2030, 1 in 6 individuals on the globe will be 60 years or older. India is also experiencing rapid population ageing. With 103 million people aged 60 and above, the elderly population of India represented 8.6% of the country's overall population in 2011 (ref. 3). By 2030, there will be 192 million elderly persons in the country<sup>4</sup>.

Ageing presents some health, social and financial challenges. Hearing loss, cataract, osteoarthritis, pulmonary diseases, diabetes, depression and dementia are some common

ailments prevalent in older people across the globe<sup>5</sup>. Cardiovascular disorders, diabetes mellitus, respiratory disorders, neurological/psychiatric problems, bone or joint diseases, and cancer are the prevalent chronic health conditions affecting the geriatric population in India<sup>6</sup>.

Mental health in older age groups is strongly influenced by neurological and psychiatric conditions. More than 20% of people 60 and older worldwide have a mental or neurological disorder. This condition is responsible for 6.6% of all disabilities (measured as disability-adjusted life years, or DALYs) among those older than 60 years of age<sup>5</sup>. In the Global Burden